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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,472	11/14/2003	Charles A. Vacanti	VAC102CON(2)	1928
23579	7590	09/26/2007		
PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE, SUITE 1200 1201 PEACHTREE STREET ATLANTA, GA 30361			EXAMINER GAMETT, DANIEL C	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 09/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/713,472

Applicant(s)

VACANTI ET AL.

Examiner

Daniel C. Gamett, PhD

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43, 44, and 54-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43, 44, 54-57 and 61 is/are allowed.
- 6) ☒ Claim(s) 58-60 and 62 is/are rejected.
- 7) ☒ Claim(s) 62 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/01/2007 has been entered.
2. Claims 43, 44, and 54-62 are under consideration.
3. In response to Applicant's request, it is hereby confirmed that the objection to the drawings set forth in the office action of 05/18/2005 has been overcome by Applicants' amendment to delete figures 2-5 and corresponding amendments to the specification on 01/10/2006.
4. All prior objection/rejections not specifically maintained in this office action are hereby withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Claim Objections

6. Claim 62 is objected to because of the following informalities: Claim 62 is a sentence fragment with no verb. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. Claims 58-60 and 62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an undifferentiated cell population in combination with a support material, wherein the support material comprises a hydrogel, does not reasonably provide enablement for an undifferentiated cell population in combination with a support material, wherein the support material is a hydrogel. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Claim 58 is dependent from claim 43, which recites a cell population in combination with a support material, wherein the structure of the support material guides the development and shape of new tissue from the cell population and resists external compressive and tensile stresses from the environment and surrounding tissues. Claim 58 is drawn to an embodiment of the combination recited in claim 43 wherein the support material *is* a hydrogel support structure. The instant specification clearly teaches that the support structure recited in claim 43 is something different from and in addition to the hydrogel, and that it is this additional structure, not the hydrogel that imparts resistance to compressive and tensile stresses. One of skill in the art would not expect that a hydrogel, by itself, would be capable of any appreciable resistance to compressive and tensile stresses. Indeed, Applicant's has pointed out in the first full paragraph of page 5 in the remarks filed 07/02/2007 that, "In the absence of such a support structure, a patient would not be able to apply any weight or stress to the hydrogel composition..." Therefore, instead of teaching the skilled artisan how to make and use the invention of claim 58, the instant specification teaches that such an

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invention would not be possible. Furthermore, by reciting that the support structure *is* a hydrogel, a logical contradiction is established in claim 59: a support structure could *comprise* a hydrogel and further comprise the additional recited materials, but resulting combined structure would not *be* a hydrogel. Claim 60 has the same contradiction as claim 59 if the recited polymeric support structure is anything other than the hydrogel itself. Finally, claim 62, insofar as it can be understood, is not enabled as it depends from claim 58, because a composition consisting only of cells and hydrogel would not resist compressive forces if used for spinal cord repair.

Conclusion

8. Claim 58-60 and 62 are rejected.
9. Claims 43, 44, 54-57, and 61 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C. Gamett, PhD whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on 571 272 0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DCG
Art Unit 1647
25 September 2007

/DAVID ROMEO/
PRIMARY EXAMINER
ART UNIT 1647